

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

Astellas Institute for Regenerative Medicine, and  
Stem Cell & Regenerative Medicine  
International, Inc.,

Plaintiffs,

v.

ImStem Biotechnology, Inc.,  
Xiaofang Wang, and  
Ren-He Xu,

Defendants.

Civil Action No. 1:17-cv-12239

Hon. Allison D. Burroughs

**STIPULATED PROTECTIVE ORDER**

Plaintiffs Astellas Institute for Regenerative Medicine (“Astellas”), and Stem Cell & Regenerative Medicine International, Inc. (“SCRMI”) and Defendants ImStem Biotechnology, Inc. (“ImStem”), Xiaofang Wang, and Ren-He Xu assert that they possess confidential information in the form of trade secrets or other confidential and proprietary business, research, development, financial, personal and/or technical information related to the subject matter of the above-captioned litigation (“Action”). The Parties bound by this Protective Order include:

1. Plaintiffs Astellas Institute for Regenerative Medicine and Stem Cell & Regenerative Medicine International, Inc. (collectively “Plaintiffs”); and
2. Defendants ImStem Biotechnology, Inc., Xiaofang Wang, and Ren-He Xu (collectively “Defendants”).

The Parties recognize that it may be necessary to disclose certain of the asserted confidential information during the course of this litigation. As a result, the Parties desire to limit

disclosure and prevent use of such information for any purposes other than the prosecution and defense of this Action. In addition, the Parties contemplate that non-parties may produce confidential information. Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, the Parties, by and through their respective undersigned counsel, hereby stipulate and agree to the request for, and entry of, the following Protective Order (hereinafter, “Order”).

## **I. DEFINITIONS**

A. *Producing Party*: The term “Producing Party” shall mean any party to this Action or any third party, including its counsel, retained experts, directors, officers, employees, business partners, or agents, who produces any Discovery Material.

B. *Discovery Material*: The term “Discovery Material” shall mean any Document (as defined below), material, item, testimony, or thing filed with or presented to the Court or produced, served, or generated during the discovery process, including, for example, exhibits, answers to interrogatories, responses to requests for admissions, responses to requests for production, subpoenas, declarations, affidavits, and deposition testimony or transcripts, and all copies, extracts, summaries, compilations, designations, and portions thereof.

C. *Confidential Information*: The term “Confidential Information” shall mean any Discovery Material designated by a Producing Party as CONFIDENTIAL that the Producing Party claims in good faith constitutes, contains, reveals, relates to, or reflects information (i) that the Producing Party would not normally reveal to third parties except in confidence, or has undertaken with others to maintain in confidence, (ii) that the Producing Party believes in good faith is significantly sensitive, or (iii) protected by a right to privacy under federal or state law or any other applicable privilege or right related to confidentiality or privacy.

D. *Highly Confidential Information:* The term “Highly Confidential Information” shall mean any Discovery Material designated by a Producing Party as HIGHLY CONFIDENTIAL that the Producing Party claims in good faith constitutes, reveals, relates to, or reflects information that contains highly sensitive financial, technical, or strategic information, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the designating party.

E. *Document:* The term “Document” shall mean every means of recording any form of communication or representation upon any tangible thing, including letters, numbers, words, pictures, sounds, or symbols, or combinations thereof, whether recorded by handwriting, printing, photostatic or photographic means, magnetic impulse, tape, computer disk, CD-ROM or any other form of electronically stored information, and all other tangible things which come within the meaning of “writing” contained in Rule 1001 of the Federal Rules of Evidence, or within the meaning of “document” or “tangible thing” contained in Rule 34 of the Federal Rules of Civil Procedure.

F. *Protected Information:* The term “Protected Information” shall mean both Confidential Information and Highly Confidential Information.

G. *Receiving Party:* The term “Receiving Party” shall mean any party to this Action, including its counsel, retained experts, directors, officers, employees, business partners, or agents, who receives any Discovery Material in this Action.

H. *Scope:* The scope of this Order shall be understood to encompass not only Protected Information which is expressly designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL, respectively, but also any information derived therefrom, including all copies, excerpts, and summaries thereof, whether partial or complete, as well as testimony and oral conversations which

reveal all or part of that information. Further, information which becomes available to any party via inspection, measuring, analyzing or testing of any sample or thing designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL pursuant to this Order, or which is prepared or derived by utilizing information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL and supplied under this Order, shall be considered CONFIDENTIAL or HIGHLY CONFIDENTIAL, as the case may be, under this Order.

## **II. PROCEDURE FOR DESIGNATING MATERIALS**

Documents, information, materials, pleadings, legal memoranda, expert statements and discovery responses, in whole or in part, may be designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” as follows:

A. In the case of Documents or any other tangible thing produced, designations shall be made by placing the legend “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” on each page of the document or on the cover or in a prominent place on any other tangible thing prior to production of the document or tangible thing;

B. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Order by appending to the file names or designators information indicating whether the file contains Confidential or Highly Confidential Information, or shall use any other reasonable method for so designating Discovery Material produced in electronic format;

C. In producing original files and records for inspection, no marking need be made by the Producing Party in advance of the inspection;

D. In the case of deposition testimony and transcripts or portions thereof, designation shall be made by a Party or third party providing such testimony either (1) on the record during the deposition, in which case the portion of the transcript of the designated testimony shall be

bound in a separate volume and marked “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” by the reporter, or (2) by captioned, written notice to the reporter and all counsel of record, given within fourteen (14) days after the reporter sends written notice to the deponent or the deponent’s counsel that the transcript is available for review, in which case all counsel receiving such notice shall be responsible for marking the copies of the designated transcript or portion thereof in their possession or control as directed by the Party, third party, or deponent. Pending expiration of the fourteen (14) days, all parties and, if applicable, any third party witnesses or attorneys, shall treat the deposition transcript as if it had been designated “HIGHLY CONFIDENTIAL.” No person shall attend the designated portions of such depositions unless such person is an authorized recipient of Protected Information under the terms of this Order or the Parties agree to such person’s attendance.

E. When a party wishes to designate as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” its own materials produced by someone else, such designation shall be made: (1) within fourteen (14) days from the date that the Party requesting the designation receives copies of such materials from the producing or disclosing entity; and (2) by written notice to all Parties to this Action and to the Producing Party, if such party is not a Party to this Action, and identifying the materials to be designated with particularity (either by production numbers or by providing other adequate identification of the specific material). Such notice may be provided by e-mail. The Parties receiving such materials agree to treat them as “HIGHLY CONFIDENTIAL” materials under this Protective Order until expiration of said fourteen (14) day period or until designation is made as set forth above within said fourteen (14) day period.

F. Each Party retains the right to subsequently re-designate documents and to require such documents to be treated in accord with such re-designations from that time forward.

### **III. CONTESTING THE DESIGNATION**

A. No Party shall be obligated to challenge the propriety of any designation by any Producing Party, and a failure to do so shall not constitute a waiver or in any way preclude a subsequent challenge in this or any other action to the propriety of such designation.

B. Any Party may contest a claim of confidentiality. Any Party objecting to the designation of any Discovery Material as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” must give outside counsel of record for the Producing Party written notice of its reasons for the objection. The Parties will attempt first to resolve the dispute on an informal basis before presenting the dispute to the Court. All items objected to shall continue to be treated as Confidential or Highly Confidential Information, according to the level of confidentiality designated by the Producing Party, pending resolution of the Parties’ dispute. If the dispute can be resolved, all Parties shall promptly be informed of the resolution. If the Parties are unable to resolve the matter informally, the Party objecting may file an appropriate motion before the Court. In response to a motion brought pursuant to this paragraph, the burden of establishing confidentiality shall be on the Party who made the claim of confidentiality, i.e., the Producing Party.

C. Entering into, agreeing to, and/or complying with the terms of this Protective Order shall not: (1) operate as an admission by any Party that any particular documents, material, or information contain or reflect currently valuable trade secrets or proprietary or commercial information; or (2) prejudice in any way the right of a Party at any time to: (a) seek a determination by the Court of whether any particular document, item, or material or piece of information should be subject to the terms of this Order; (b) seek relief on appropriate notice from any provision(s) of this Protective Order, either generally or as to any particular document, item, or piece of information; (c) object to any discovery request, including the right to assert that no discovery

should be had of certain documents or information; (d) seek a higher level of protection than provided for by this Protective Order if the party believes that unique circumstances warrant that higher level of protection; or (e) seek documents or other information from any source.

#### **IV. RESTRICTION ON DISCLOSURE AND USE**

A. *Confidentiality.* Protected Information and the information derived from such Protected Information (excluding information which is derived lawfully from an independent source) shall be kept confidential and shall not be used for any purposes other than the prosecution and defense of this Action, including but not limited to use in other litigation, for business purposes, or for patent prosecution. This information also shall not be given, shown, made available, discussed, or otherwise communicated in any manner, either directly or indirectly, to any person not authorized to receive the information under the terms of this Order, subject to the provision in Section VI. Any person found to have made an impermissible use of any Protected Information produced in this Action may be subject to, without limitation, appropriate civil penalties, including for contempt of court.

B. *Maintenance of Protected Information.* Protected Information shall be maintained by the Receiving Party at a location and under circumstances to ensure that access is limited to those persons entitled to have access under this Order.

C. Notwithstanding the provisions in Sections V and VI, a document designated CONFIDENTIAL or HIGHLY CONFIDENTIAL may be disclosed, at a deposition or otherwise, to any current employee of the Producing Party or to any author or recipient of the Protected Information identified on the face of the document, unless a different result is agreed to by counsel for the Parties.

D. Counsel for a Party may also disclose Protected Information to any actual or potential witness provided counsel has obtained prior written consent of the Producing Party.

Notwithstanding the provisions of Sections V and VI, consent need not be obtained if the person is an author, recipient or current custodian of the document or item marked CONFIDENTIAL or HIGHLY CONFIDENTIAL, or a corporate designee of the Producing Party pursuant to Federal Rule of Civil Procedure 30(b)(6).

E. *Depositions.* At any deposition session, when counsel for a Party or the deponent deems that the answer to a question will result in the disclosure of Protected Information, counsel shall have the option, in lieu of taking other steps available under the Federal Rules of Civil Procedure, to request that all persons other than the court reporter, counsel, and individuals specified in Section V hereof who have access to the pertinent category of Protected Information, exit the deposition room during the Confidential or Highly Confidential portion of the deposition. The failure of such other persons to comply with such requests shall constitute substantial justification for counsel to instruct the witness, or for the witness to elect, not to answer the question pending.

F. *Trial and other public proceedings.* Any use of Protected Information at trial shall be governed by a separate agreement or order. In the event that any Protected Information is used in any pre-trial court hearing or proceeding in this Action, and there is any dispute as to whether such material continues to be Confidential or Highly Confidential, the Parties will meet and confer to resolve such dispute. The Parties shall confer and attempt to agree before any trial or other hearing on the procedure under which Protected Information may be introduced into evidence or otherwise used at such trial or hearing, taking in to account the need to ensure that any proceeding before the Court is fair, efficient, and consistent with the public interest. Upon reaching agreement, the Parties shall give notice of the terms of such agreement to each non-party producing any Protected Information that may be used or introduced at such trial or hearing.



Absent agreement, the Court shall be asked to issue an order governing the use of such Protected Information at trial or hearing upon reasonable notice to all Parties and non-parties who have produced such information. The Parties shall provide non-parties with notice of potential use at trial of any Protected Information produced by them if, and when, they are listed as potential exhibits in the required filings prior to commencement of trial. The Parties shall give such notice as soon as practicable after Protected Information that is not listed on the exhibit list is determined to be used by counsel for a Party in the course of examination or cross-examination at trial.

G. A Producing Party is free to do whatever it desires with its own Protected Information.

H. Nothing in this Protective Order shall be construed to prevent counsel from advising their clients with respect to this case based in whole or in part upon Protected Information, provided counsel does not disclose this information itself except as provided for in this Order.

## **V. ACCESS TO CONFIDENTIAL INFORMATION**

A. Protected Information shall be available only to the following persons subject to the terms of Section VI:

1. One approved in-house counsel of a Party or a Party affiliate, or an entity in privity with a Party in connection with this Action, who shall be identified by written notice to each other party at least ten (10) business days before receiving any disclosure of Protected Information. The notice shall include the in-house counsel's title or position and duties and responsibilities of the individual and shall include a signed acknowledgement of Protective Order, which is attached as Exhibit A. The in-house counsel may not participate in competitive decision-making or patent prosecution concerning technology concerning methods for generating mesenchymal stem cells from embryonic stem cells, cells generated by these methods, and the use

of cells generated by these methods. If the need arises, a party may replace an in-house counsel entitled to receive Protected Information with another of its in-house counsel by first providing the advance notice set forth in this paragraph..

2. Outside litigation counsel of record, who have entered an appearance for a Party in this Action, and, if the attorney of record is a member of a law firm, the attorneys, paralegals, and staff of the law firm to whom it is reasonably necessary to disclose the Discovery Materials in this Action (collectively “Outside Counsel”);

3. Copy and clerical litigation, document management, and electronic data support services working at the direction of Outside Counsel;

4. Judges, Magistrate Judges, law clerks, and clerical personnel of the Court before which this Action is pending or qualified court reporters;

5. Subject to the notice and objection period of Section VI(A) below, consultants or experts and their clerical staff, excluding employees, officers or directors of a named Party or owners of more than a two-percent interest in a named Party, retained by any of the Parties or their counsel to consult or testify in the case;

6. Jury research consultants and mock jurors and judges who have signed an undertaking or agreement not to publically disclose Protected Information and to keep any information concerning Protected Information confidential;

7. Litigation support consultants engaged to provide services relating to document processing, indexing, scanning, imaging or storage, translation, interpretation, document review, demonstrative exhibits, graphics, charts, animations, design services, and/or non-technical trial services, provided they acknowledge that they will abide by this Order by signing the acknowledgement attached as Exhibit A. Where a company or firm is retained for such litigation

support services, it shall be sufficient for purposes of this Order that a representative of such company or firm sign the acknowledgement attached as Exhibit A on behalf of the company or firm. Such representative shall be responsible for ensuring that any employee, consultant, or representative of that company or firm who receives Protected Information abides by the provisions of this Order;

8. Court reporters and videographers taking testimony involving information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL and necessary stenographic and clerical personnel thereof;

9. Persons who have been retained by a party to provide translation or interpretation from one language to another, provided they acknowledge that they will abide by this Order by signing the acknowledgement attached as Exhibit A; and

10. Any other person authorized to receive Protected Information by order of the Court or by written agreement of the parties.

B. Material produced and marked as Confidential Information or Highly Confidential Information may be disclosed only to individuals identified in Section V(A), and to any other persons as counsel for the Producing Party agrees in advance or as otherwise Ordered by the Court.

## **VI. CONDITIONS ON ACCESS TO CONFIDENTIAL INFORMATION**

A. *Consultants and Experts.* Prior to a party giving, showing, disclosing, making available or communicating Protected Information to any expert or consultant under Section V(A)(5) above, the party shall:

1. Serve a notice on all other parties, identifying the expert or consultant and the expert's or consultant's business address, business telephone numbers, present employer and position (along with a job description), consulting activities and job history for the past three years, and past or present relationship, if any, with any parties in this Action and their affiliates.

Furthermore, the most recent curriculum vitae or resume of the expert or consultant shall be provided under this Section. If the most recent curriculum vitae or resume of the expert or consultant provides the information required under this paragraph, then the information need not be separately provided.

2. Include with such notice, a copy of the acknowledgment of Protective Order, attached as Exhibit A, signed by the expert or consultant and including all the information to be completed therein. The notified parties shall be entitled to object to disclosure of Protected Information to the expert or consultant within five (5) business days after receipt of the notice and acknowledgment of Protective Order by stating specifically in writing the reasons why such expert or consultant should not receive Protected Information.

3. If the Parties are unable to agree on disclosure to the expert or consultant, the Party objecting to such expert or consultant may apply to the Court for an order that disclosure is improper within ten (10) business days of its objection. The burden of establishing the validity of such written objections rests with the objecting Party. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn.

4. No disclosure of Protected Information shall be made to the proposed expert or consultant until the time for serving objections to that expert or consultant has passed, or, in the event that a written objection is timely served and a motion to prevent disclosure is filed, until such time as the Court has made a ruling thereon, and then, only in accordance with such ruling.

5. The filing and pendency of objections shall not limit, delay, or defer any disclosures of Protected Information to persons as to whom no such objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting Party's ability to conduct such discovery.

B. *Patent Prosecution.* “Prosecution Bar Materials” means: all Highly Confidential Information produced by a Party or non-party EXCEPT for information that lawfully is or becomes publically available, including patents and published patent applications.

1. Any person who has reviewed some or all of an opposing Party’s Prosecution Bar Materials shall not, for a period commencing upon receipt of such information and ending one (1) year following the conclusion of this Action (including any appeals), engage in any Prosecution Activity (as defined below) on behalf of a Party in this case.

2. “Prosecution Activity” shall include any activity relating to the prosecution of patents or patent applications relating to: methods for generating mesenchymal stem cells from embryonic stem cells, cells generated by these methods, and the use of cells generated by these methods. For the purposes of this paragraph, “prosecution” includes directly or indirectly drafting, amending, advising on drafting or amending, or otherwise affecting the scope of patent claims. Prosecution includes, for example, original prosecution, reissue, or reexamination. To avoid any doubt, “prosecution” as used in this paragraph does not include representing a party challenging or defending a patent before a domestic or foreign agency (including, but not limited to, a reissue protest, *ex parte* reexamination or *inter partes* reexamination, *inter partes* review, or covered business method review). Nothing in this paragraph shall prevent any attorney from sending non-confidential prior art, without additional input or consultation, to an attorney involved in patent prosecution for purposes of ensuring that such prior art is submitted to the U.S. Patent and Trademark Office (or any similar agency of a foreign government) to assist a patent applicant in complying with its duty of candor. Any attorney for or representing any Party and any person associated with any Party who has access to Prosecution Bar Materials shall not directly or indirectly use and/or disclose Prosecution Bar Materials to any individuals involved in drafting,

amending, or prosecuting patent claims pertaining to methods for generating mesenchymal stem cells from embryonic stem cells, cells generated by these methods, and the use of cells generated by these methods.

C. The foregoing restrictions of this Section VI(B) shall apply only to individuals, and not to the firms or organizations by which they are employed, nor to individuals who received access to Prosecution Bar Materials solely in their capacity as clerical staff. Nothing in this paragraph shall be construed as a waiver of the other provisions of this Order, including but not limited to those provisions restricting the use and disclosure of Prosecution Bar Materials.

D. *Authorization and Acknowledgment.* Counsel for the Receiving Party shall keep in his or her files an original of each acknowledgment of Protective Order executed by an individual required to execute an acknowledgement prior to receipt of the Producing Party's Protected Information until sixty (60) calendar days after the final termination of this Action.

## **VII. PROCEDURES FOR FILING PAPERS WITH PROTECTED INFORMATION**

A. The parties must seek to file any Protected Information under seal. Counsel for all parties shall follow all applicable Local Rules, including Local Rule 7.2 regarding motions for impounding confidential materials, and customs for the Court when filing Protected Information under seal.

B. The parties must seek to file all papers with the Court, including but not limited to pleadings and memoranda of law, which include, in their entirety or in part, any Protected Information under seal in accordance with the terms and procedures set forth in this Order, including the procedures for filing materials set forth above in Section VII(A). Counsel for the party filing papers with Protected Information shall be responsible for appropriately designating the papers filed with the Court as having Confidential Information or Highly Confidential Information. Such papers shall be subject to the terms of this Order.

C. Nothing herein shall be construed to affect in any manner the admissibility at trial of any document, testimony, or other evidence.

#### **VIII. REDACTED FILINGS OF PAPERS WITH PROTECTED INFORMATION**

Redacted versions of papers with Protected Information filed under seal must be filed with the Court, where practicable, in accordance with all applicable Local Rules, including Local Rule 7.2, and normal procedures and made publicly available provided that:

- A. All Protected Information set forth in the papers is deleted or obscured; and
- B. Redacted versions of the papers are clearly marked “Public Version Confidential Material Omitted.” Redacted versions of the papers also must clearly identify each place where information or exhibits have been deleted.

#### **IX. UNINTENTIONAL FAILURE TO DESIGNATE**

The inadvertent failure by a Producing Party to designate specific documents or materials as containing Protected Information shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. If, through inadvertence, a Producing Party provides any Protected Information pursuant to this litigation without designating and marking the Protected Information as CONFIDENTIAL or HIGHLY CONFIDENTIAL, the Producing Party may subsequently inform the Receiving Party of the confidential nature of the disclosed Protected Information, and the Receiving Party shall treat the disclosed Protected Information as CONFIDENTIAL or HIGHLY CONFIDENTIAL upon receipt of written notice from the Producing Party, to the extent the Receiving Party has not disclosed this Protected Information. Disclosure of such Protected Information to persons not authorized to receive that material prior to receipt of the confidentiality designation shall not be deemed a violation of this Order. However, in the event the material has been distributed in a manner inconsistent with the categorical designation, the Receiving Party will take the reasonable steps necessary to conform distribution

to the categorical designation, i.e., by retrieving all copies of the Protected Information, or notes or extracts thereof, in the possession of the persons not authorized under this Order to possess such Protected Information and advising the person to whom disclosure was made that the material is confidential and should be treated as provided in the Order. For purposes of this provision, all failures to designate that a Party claims were inadvertent shall be deemed to be inadvertent.

#### **X. UNINTENTIONAL DISCLOSURE OF PROTECTED INFORMATION**

If Protected Information, or any portion thereof, is disclosed by the Receiving Party, through inadvertence or otherwise, to any person or party not authorized under this Protective Order, then the Receiving Party shall use its best efforts to retrieve immediately all copies of such Protected Information, and to bind such person to the terms of this Order. In such event, the Receiving Party shall also (a) promptly inform such person of all the provisions of this Order; (b) identify such person immediately to the Producing Party; and (c) request such person to execute the acknowledgment of Protective Order, attached as Exhibit A.

#### **XI. INFORMATION NOT COVERED BY THIS ORDER**

The restrictions set forth in this Order shall not apply to information which is in the possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party, or which lawfully comes into the possession of or becomes known to the Receiving Party or lawfully comes into the possession of or otherwise becomes known to the public after the date of its transmission to the Receiving Party, provided that such information does not come into the possession of the Receiving Party or become publicly known by any act or omission which would be in violation of this Order, a similar Order with respect to another party, or any other duty of confidentiality.



## **XII. RESPONSIBILITY OF ATTORNEYS**

Outside Counsel of record shall be responsible for providing a copy of this Order to all persons entitled access to Protected Information under Section V and to employ reasonable measures to control duplication of, access to, and distribution of copies of materials so designated. No person shall duplicate any Protected Information except, as contemplated by this Order, for use as exhibits at depositions, in connection with court filings or, as necessary, by counsel, experts or consultants approved under Sections V and VI for use as working copies. All copies, extracts and translations must be appropriately marked and are subject to Section XIII of this Order.

## **XIII. FINAL DISPOSITION**

Upon termination, settlement or final judgment of this litigation including exhaustion of all appeals, the originals and all copies of Protected Information shall be either destroyed or turned over to the Producing Party, or to their respective outside counsel, within sixty (60) calendar days, except that a party is not obligated to return or destroy Protected Information that may be contained on electronic back-up tapes or other archival media, which should be treated in accordance with standard retention policies, i.e., which are not retained indefinitely without being overwritten. Retained counsel also may retain pleadings, legal memoranda, expert reports, attorney and consultant work product, and depositions for archival purposes that contain or refer to Confidential or Highly Confidential provided that such counsel and employees of such counsel shall not disclose such material to any person, except pursuant to court order. Nothing shall be interpreted in a manner that would violate any applicable canons of ethics or codes of professional responsibility. If Protected Information is destroyed pursuant to this paragraph, outside counsel for the Receiving Party shall provide to outside counsel for the Producing Party a certification that the destruction was performed.

#### **XIV. DISCOVERY FROM THIRD PARTIES**

If discovery is sought of a person not a Party to this Action (third party) requiring disclosure of such third party's Protected Information, the Protected Information disclosed by any such third party will be accorded the same protection as the Parties' Protected Information, and will be subject to the same procedures as those governing disclosure of the Parties' Protected Information pursuant to this Order.

#### **XV. ADMISSIBILITY**

Nothing herein shall be construed to affect in any way the evidentiary admissibility of any document, testimony, or other matter at any court proceeding related to this matter. The marking of Confidential Information as CONFIDENTIAL or Highly Confidential Information as HIGHLY CONFIDENTIAL pursuant to this Order shall not, for that reason alone, bar its introduction or use at any court proceeding related to this matter pursuant to such terms and conditions as the Court may deem appropriate, consistent with the need for a complete and accurate record of the proceedings; provided, however, that every effort shall be made, through the use of procedures agreed upon by the Parties or otherwise, to preserve the confidentiality of Confidential Information marked as CONFIDENTIAL or Highly Confidential Information marked as HIGHLY CONFIDENTIAL.

#### **XVI. NON-PARTY REQUEST/SUBPOENA OF CONFIDENTIAL INFORMATION**

If a Receiving Party receives a subpoena or other compulsory process from a non-party to this Order seeking production or other disclosure of a Producing Party's Protected Information, that Receiving Party shall give written notice to outside counsel of record for the Producing Party within ten (10) business days after receipt of the subpoena or other compulsory process identifying the specific Protected Information sought and enclosing a copy of the subpoena or other compulsory process. If written notice to the Producing Party must be provided by an earlier time

to allow the Producing Party to timely seek a protective order, the Receiving Party must provide written notice by that earlier time. If the Producing Party timely seeks a protective order, the Receiving Party to whom the subpoena or other compulsory process was issued or served shall not produce the Protected Information requested prior to receiving a Court order or consent of the Producing Party. In the event that Protected Information is produced, other than by Court order, to the non-party in accordance with this provision, such material shall be treated as Confidential Information or Highly Confidential Information pursuant to this Order.

## **XVII. NON-RELEVANT SUBJECT-MATTER REDACTIONS**

The Parties, aware that certain non-responsive information may be highly sensitive, further agree that non-responsive information that meets the criteria for either Confidential or Highly Confidential Information in a responsive document may be redacted solely on the basis of non-responsiveness where the document can be redacted without obscuring otherwise responsive information. For example, a memo, report, document, presentation, spreadsheet, or email may contain both responsive information and non-responsive information about other research programs or products that is Confidential or Highly Confidential. Such non-responsive information may be redacted. When a Party redacts non-responsive Confidential or Highly Confidential Information, that redaction will be labeled “Redacted – Relevancy.”

Where a family of documents contains responsive information and an attachment in that family is non-responsive, the entire non-responsive attachment may be withheld provided that a slip-sheet containing basic information about the withheld document, including the type of document withheld and number of pages, is produced that indicates the document was withheld based on relevancy.

Relevancy redactions are subject to the same burdens and restrictions as designations for confidentiality, and may be challenged in the manner set forth in Section III. Further, in the event

a party contests another party's relevancy redaction, the burden shall be upon the redacting party to explain the redaction if questioned and justify the redaction if challenged in Court.

## **XVIII. PRIVILEGE**

A. *Logs*: Consistent with the Federal Rules of Civil Procedure, a Party withholding or redacting any responsive document on the grounds of privilege, immunity, or any similar claim shall provide to the receiving party a privilege log, except that:

1. the Parties shall have no obligation to log information generated on or after the November 13, 2017 (i.e., date the Complaint was filed); and

2. activities undertaken in compliance with the duty to preserve information (including, but not limited to, litigation hold letters) are protected from disclosure under Fed. R. Civ. Proc. 26(b)(3)(A) and (B) and need not be included in the privilege log.

B. *Log Format*: For each document withheld or redacted, the privilege log shall contain the following information: (i) the date of the document; (ii) the identity of all persons who authored, signed, or otherwise prepared the document; (iii) the identity of all persons designated as addressees or copyees; (iv) a description of the contents of the document that, without revealing information itself privileged or protected, is sufficient to understand the subject matter of the document and the basis of the claim of privileged or immunity; (v) the type or nature of the privilege asserted (e.g., attorney-client privilege, work product doctrine, etc.); and (vi) for redacted documents only, the Bates numbers corresponding to the first and last page of any document redacted. For all individuals listed on a log whose role as an attorney is the basis for a claim of privilege, the privilege log shall contain some indication that the individual is an attorney (for example, an asterisk next to each attorney's name).

C. *Redactions*: When a Party redacts information that is protected by the attorney-client privilege or work product protection ("Privileged Information"), that redaction will be

labeled “Redacted – Privilege.”

D. *Clawback*: This Order is entered pursuant to Rule 502(d) of the Federal Rules of Evidence. Subject to the provisions of this Order, if the Producing Party discloses information in connection with this Action that the Producing Party thereafter claims to be Privileged Information, the disclosure of that Privileged Information will not constitute or be deemed a waiver or forfeiture—in this Action or any other action—of any claim of privilege or work product protection that the Producing Party would otherwise be entitled to assert with respect to the Privileged Information and its subject matter.

1. This Order protects *any* disclosure of Privileged Information, whether that disclosure is inadvertent or otherwise.

2. Each party is entitled to decide, in its sole discretion, the appropriate degree of care to exercise in reviewing materials for privilege. Irrespective of the care that is actually exercised in reviewing materials for privilege, the Court hereby orders that disclosure of Privileged Information in discovery conducted in this Action shall not waive any claim of privilege or work product protection that the Producing Party would otherwise be entitled to assert with respect to the Privileged Information and its subject matter.

3. A Producing Party must notify the party receiving the Privileged Information (“the Receiving Party”), in writing, that it has disclosed that Privileged Information without intending a waiver by the disclosure following in the procedure in Section XIX. Upon receipt of notification, the Receiving Party shall (a) destroy or return all copies, electronic or otherwise, of such document or other information; (b) not use or disclose the document or information until the claim of privilege or work product protection is resolved; and (c) shall provide a certification that it has—to the best of its knowledge—destroyed or returned all copies of such document or other

information and will cease further review, dissemination, and use of the Privileged Information following the procedure in Section XIX.

4. This Order shall be interpreted to provide the maximum protection allowed to the Producing Party by Federal Rule of Evidence 502(d). The provisions of Federal Rule of Evidence 502(b)(2) are inapplicable to the production of Privileged Information under this Order. However, if for any reason a Court finds that this Section is inapplicable to Privileged Information, then Rule 502(b) will apply in its absence.

E. *Challenges to Clawbacks*: Nothing in this Order shall limit the Receiving Party's right to challenge (on grounds unrelated to the fact or circumstances of the disclosure) the Producing Party's claim that Privileged Information is protected from disclosure by the attorney-client privilege or work product doctrine. The Parties agree to use the procedure in Section XIX for any such challenges. If, after undertaking an appropriate meet-and-confer process, the Parties are unable to resolve any dispute they have concerning the protection of documents for which a claim of privilege has been asserted, the Receiving Party may file the appropriate motion or application as provided by the Court's procedures to compel production of such material. Any Privileged Information submitted to the Court in connection with a challenge to the Producing Party's claim of attorney-client privilege or work product protection shall not be filed in the public record, but rather shall be redacted, filed under seal, or submitted for in camera review.

## **XIX. DISCLOSURE OF PRIVILEGED INFORMATION**

A. Notwithstanding anything to the contrary in Rule 26(b)(5)(A) and (B) of the Federal Rules of Civil Procedure, the inadvertent production or disclosure of any document or tangible thing (including information) that should have been withheld subject to a claim of attorney-client privilege or work product immunity, or other privilege or immunity, shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claims of privilege or work product

immunity. In such an event, the Producing Party shall send to each receiving party a written request for return of the inadvertently produced or disclosed document or thing within five (5) business days after becoming aware of such inadvertent or mistaken production. Within five (5) business days of receiving a written request to do so from the Producing Party, the Receiving Party shall: (a) return to the producing party any documents or tangible items that the Producing Party represents are covered by a claim of attorney-client privilege or work-product immunity, or other privilege or immunity, and were inadvertently or mistakenly produced; (b) destroy any extra copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information, including any electronic records thereof; and (c) shall provide a certification that it has—to the best of its knowledge—destroyed or returned all copies of such document or other information and will cease further review, dissemination, and use of the Privileged Information. The Receiving Party shall not utilize the information contained in the inadvertently produced documents or things for any purpose, or disseminate or transmit such information.

1. If the Receiving Party wishes to contest that any such document or thing is protected from disclosure by the attorney-client privilege, work product immunity or other privilege or immunity from discovery, it shall so notify the Producing Party in writing when the document or thing is returned to the Producing Party (“Notice of Designation”).

2. Within five (5) business days after receiving a Notice of Designation, the Producing Party shall provide to the Receiving Party for each document or thing a description of the basis for the claim of privilege or immunity.

3. Within five (5) business days after receiving such description, the Receiving Party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the procedures set forth in Local Rule 37.1

for resolution of discovery disputes. The party claiming the privilege or immunity shall have the burden of proving that such privilege or immunity exists.

4. With respect to documents and things subsequently generated by a Receiving Party, which documents and things contain information derived from such inadvertently produced documents and things, if the Receiving Party does not notify the Producing Party that the Receiving Party disputes the claims of attorney-client privilege or work-product immunity, or if the Court rejects any challenge by the Receiving Party to the privileged status of the inadvertent production, the Receiving Party shall either destroy the derivative documents and things or redact from them all such derivative privilege or work-product information in a manner such that the derivative information cannot in any way be retrieved or reproduced.

5. If, in a deposition, hearing, or other proceeding, the party who made the inadvertent production or disclosure makes a request on the record for return of the inadvertently produced or disclosed document or thing within a reasonably prompt period of time after recognizing that the information has been produced or disclosed, all copies of the inadvertently produced or disclosed document or thing present at the deposition, hearing, or other proceeding shall immediately be sequestered and there shall be no further use of the inadvertently produced or disclosed document or thing. For the avoidance of any dispute, the marking of an inadvertently produced or disclosed document or thing as an exhibit at deposition, hearing, or other proceeding has no bearing on the timeliness of the request for return.

B. The procedures set forth in this paragraph for challenging the privileged status of an inadvertent production shall not result in any waiver of the attorney-client privilege, the work product immunity, or any other privilege or immunity.



C. For purposes of this provision, any disclosure of information that Party claims is privileged or subject to work product protections shall be deemed to be inadvertent.

**XX. NO LIMITATION OF OTHER RIGHTS**

This Order shall be without prejudice to the right of any party to oppose production of any information on any and all grounds other than confidentiality.

**XXI. RELEASE FROM OR MODIFICATION OF THIS ORDER**

This Order is entered without prejudice to the right of any Party to apply to the Court at any time for additional protection, or to release, rescind, or modify the restrictions of this Order, to determine whether a particular person shall be entitled to receive any particular information or to seek relief from inadvertent disclosure of privileged or work-product information. This Order does not preclude all of the Parties to this Order from entering into any stipulation (in writing or on the record) constituting a modification of this Order. On any motion seeking disclosures beyond those authorized by this Order, the burden will be on the Receiving Party to justify the disclosure.

**XXII. NO CONTRACT**

To the extent that the Parties have agreed on the terms of this Order, such stipulation is for the Court's consideration and approval as an Order. The Parties' stipulation shall not be construed to create a contract between the Parties or between the Parties and their respective counsel.

**XXIII. EFFECTIVE DATE**

Documents that have been produced in this case on a Confidential or Highly Confidential basis prior to the entry of this Order shall henceforth be subject this Order.

**XXIV. TERMINATION**

The termination of this Action shall not automatically terminate the effectiveness of this Order and persons subject to this Order shall be bound by the confidentiality obligations of this

Order until the Producing Party agrees otherwise in writing or this Court (or any other court or competent jurisdiction) orders otherwise.

Dated: April 22, 2019

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**SO ORDERED.**

April 23, 2019

/s/ Allison D. Burroughs  
ALLISON D. BURROUGHS  
U.S. DISTRICT JUDGE

**EXHIBIT A**  
UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

Astellas Institute for Regenerative Medicine, and  
Stem Cell & Regenerative Medicine International,  
Inc.,

Plaintiffs,

v.

ImStem Biotechnology, Inc., Xiaofang Wang, and  
Ren-He Xu,

Defendants.

CASE NO. 1:17-CV-12239

**SUBSCRIPTION TO PROTECTIVE ORDER—  
INDEPENDENT EXPERT OR CONSULTANT**

I, \_\_\_\_\_, declare that:

1. My address is \_\_\_\_\_ and the name and address of my  
present employer is \_\_\_\_\_.

2. My present occupation or job description is \_\_\_\_\_.

3. In addition to other job functions, I am working as a consultant to  
\_\_\_\_\_.

4. My relationship to \_\_\_\_\_ is  
\_\_\_\_\_.

5. I have received a copy of the Protective Order in this Action.

6. I have carefully read and understand the provisions of the Protective Order, agree  
to be bound by them, and specifically agree I will not use or disclose to anyone any of the contents

of any Confidential or Highly Confidential information received under the protection of the Protection Order in violation thereof.

7. I understand that I am to retain all copies of any of the materials that I receive that have been so designated as Confidential or Highly Confidential in a container, cabinet, drawer, room, or other safe place in a manner consistent with the Protective Order and that all copies are to remain in my custody until I have completed my assigned or legal duties. I will return or destroy all Confidential or Highly Confidential information that comes into my possession or that I have prepared relating thereto, to counsel for the party by whom I am retained. I acknowledge that such return or the subsequent destruction of such materials shall not relieve me from any of the continuing obligations imposed upon me by the Protective Order.

8. I consent to the exercise of personal jurisdiction by this Court in connection with this Declaration and my obligations under the Protective Order.

9. I declare under penalty of perjury that the foregoing is true and correct.

Executed this \_\_\_\_ day of \_\_\_\_\_, 20\_\_ at \_\_\_\_\_  
in the State of \_\_\_\_\_.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Print Name)